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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of		:	
Wolfgang HEIL et al.		:	Group Art Unit: Unknown
Serial No.:	09/757,688	:	Examiner: Unassigned
Filed:	January 11, 2001	:	
For:	DROSPIRENONE FOR HORMONE REPLACEMENT THERAPY		

SUPPLEMENTAL PRELIMINARY AMENDMENT

Assistant Commissioner for Patents
Washington, DC 20231

Sir:

Further to our Preliminary Amendment filed February 23, 2001, please amend the above-identified application as follows:

In the Claims:

Please revise claims 77, 81, 89, and 94 as follows:

77. (Amended) A pharmaceutical composition comprising

as a first active agent, an estrogen (or naturally or synthetic derivative thereof) in sufficient amounts to treat diseases, disorders and symptoms associated with deficient endogenous levels of estrogen in women, and

as a second active agent, 6β,7β;15β;16β-dimethylene-3-oxo-17α-preg-4-ene-21,17-carbolactone (drospirenone) in sufficient amounts to protect the endometrium from the adverse effects of estrogen,

together with a pharmaceutically acceptable excipient or carrier.

81. (Amended) A composition according to claim 77, wherein the estrogen is selected from the

group consisting of estradiol, estradiol sulfamates, estradiol valerate, estradiol benzoate, ethinyl estradiol, estrone, estriol, estriol succinate and conjugated estrogens, including conjugated equine estrogens such as estrone sulfate, 17β-estradiol sulfate, 17α-estradiol sulfate, equilin sulfate, 17β-dihydroequilin sulfate, 17α-dihydroequilin sulfate, equilenin sulfate, 17β-dihydroequilenin sulfate and 17α-dihydroequilenin sulfate or mixtures thereof.

89. (Amended) A pharmaceutical composition comprising

as a first active agent estradiol in amounts corresponding to a daily dose of 1 to 3 mg to treat diseases, disorders and symptoms associated with deficient endogenous levels of estrogen in women,

and as a second active agent 6β,7β;15β;16β-dimethylene-3-oxo-17α-preg-4-ene-21,17-carbolactone (drospirenone) in amounts corresponding to a daily dose of 1 to 3.5 mg to protect the endometrium from the adverse effects of estrogen,
together with a pharmaceutically acceptable excipient or carrier.

94. (Amended) A method according to claim 90, wherein the estrogen is selected from the group consisting of estrogen is selected from the group consisting of estradiol, estradiol sulfamates, estradiol valerate, estradiol benzoate, ethinyl estradiol, estrone, estriol, estriol succinate and conjugated estrogens, including conjugated equine estrogens such as estrone sulfate, 17β-estradiol sulfate, 17α-estradiol sulfate, equilin sulfate, 17β-dihydroequilin sulfate, 17α-dihydroequilin sulfate, equilenin sulfate, 17β-dihydroequilenin sulfate and 17α-dihydroequilenin sulfate or mixtures thereof.

REMARKS

The Preliminary Amendment filed February 23, 2001, inadvertently omitted the α and β symbols due to clerical error. The amendments are not new matter.

Attached hereto is a marked-up version of the changes made to the claims by the current amendment. The attached page is captioned "**Version with markings to show changes made**."

Respectfully submitted,

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Date: March 29, 2001

VERSION WITH MARKINGS TO SHOW CHANGES MADE

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together with a pharmaceutically acceptable excipient or carrier.

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